



IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

QUARTERLY CALL FOR HRPPS

April 26, 2019

- User Training
- Study Support

*Natalie
Dilts*



- System Development
- Data analysis

*Adoma
Manful*



- Project Manager

*Emily
Serdos*



- Site Onboarding
- Study Support

*Bridget
Swindell*



- User Support
- Study Support

*Linda
Tan*



QUARTERLY CALL AGENDA – HRPPs



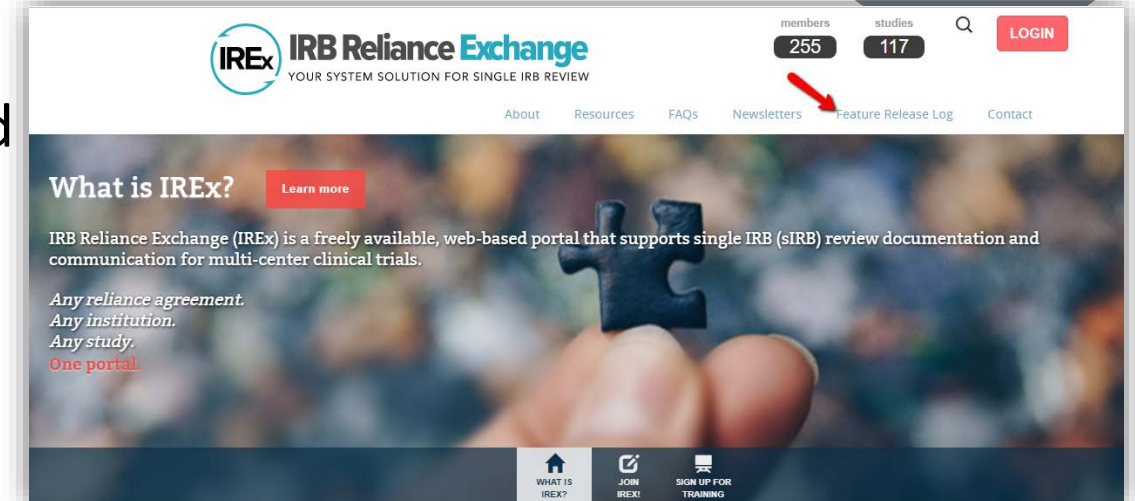
- Welcome & Reminders
- Tracking Letters of Indemnification (LOIs)
- Exporting the Status Summary Tab
- Managing FWAs Sites Engaged on a Study
- Updated Resources

Reminders from the Last Call

IN CASE YOU MISSED IT...



- Catch IREx improvements as they are released
 - Check out the [IREx Feature Release Log](#)
 - Read our monthly [IREx Newsletter](#)



- New to IREx or need a refresher? Join a training!
 - [Reviewing IRB trainings](#) – setting up your study in IREx
 - [Relying HRPP trainings](#) – using IREx to document reliance/ local considerations
 - [Lead Study Teams/Coordination Centers](#) – using IREx to support your sIRB study
 - Can't make the monthly trainings? [Request a demo](#) for your team

Tracking Letters of Indemnification (LOIs)

TRACKING LETTERS OF INDEMNIFICATION (LOIs)



- **Some institutions require an LOI given that SMART IRB is silent on indemnification**
- **IREx will allow for tracking of institutional-level LOIs**
 - Cannot have different LOIs for different studies
- **Internal and External LOI tracking**
 - Sites who have signed your LOI
 - External LOIs you signed

TRACKING LETTERS OF INDEMNIFICATION (LOIs)



*No memorization needed-
LOI Quick Guide available
on the resources page*

Updated February 20, 2019

Using IREx to Track Letters of Indemnification (LOIs)

Some institutions require a Letter of Indemnification (LOI) when serving as the Reviewing IRB using the SMART IRB Agreement, which is silent on indemnification (see section 4.11). IREx allows Reviewing IRBs to track institutions with which they have an executed LOI. The LOI can be a unique agreement between the Reviewing IRB and another institution; however, only one executed LOI can be tracked per institution.

HOW DO I TRACK WHO HAS SIGNED AN LOI WITH MY INSTITUTION?

- Click the blue **Agreements** button on the home page.
- On the **Your Institution's LOI** tab, enter the name of your LOI and upload a template.

Your Institution's LOI

External LOIs

Your Letter of Indemnification (LOI)

The name you provide below will be listed on the official Notification of Reliance letter when a site indicates reliance.

Name

Template

Choose File No file chosen

Your Institution's LOI

External LOIs

The University of the Bay IRB Letter of Indemnification (Addendum to the SMART IRB Master Agreement) v. 06/13/2018

Add A Site

Select a site

Date Sent

Date Executed

Agreement

Choose File No file chosen

Notes

Save Site

LOI Sites

Name	Date Sent	Date Executed	Document	Status
Peabody Institute of Medicine	8/15/2018	8/15/2018	LOI - LeadIRBsigned_IRBExecuted.pdf	Completed
University of the Bay	Aug 15 - Sent LOI to PI			In Progress

Aug 15 - Sent LOI to PI

Sept 12 - LOI routed to Peabody Legal Office for Review

Sept 25 - Call with Peabody Legal to review LOI. Changes requested cannot be accommodated.

Sept 30 - Peabody Legal has agreed to sign LOI after internal discussion.

Oct 8 - Received signed LOI from study coordinator.

University of the Bay

Save Site

Your Institution's LOI

External LOIs

External LOIs

These are other institutions' LOIs which you have executed

Site	Date Executed	Agreement
Carnegie University Medical Center	03/03/2018	LOI - LeadIRBsigned.docx
Cornell University	05/01/2018	Not completed
Cumtong Medical Center of Ohio		Not completed

NOTE: THE NAME YOU PROVIDE WILL BE LISTED ON THE OFFICIAL NOTIFICATION OF RELIANCE LETTER WHEN A SITE INDICATES RELIANCE.

The LOI column will appear on the status summary tab indicating which of the listed sites have signed your LOI.

2. To update a site's LOI status, click the grey "X" beside a site's name or use the **Manage LOI** button at the top of the status summary.

3. If institutions are added to the study that are not already an institution on your LOI tracker, they will be added.

AS A RELYING SITE, HOW DO I...?

Complete Agreement to see which Reviewing IRB... until you complete the required

Available now in IREx!

TRACKING LETTERS OF INDEMNIFICATION (LOIs)



Step 1: Add the LOI your institution requires when serving as the Reviewing IRB

Find a Study

by Name:

by Sponsor:

Create a Study

find

Your Institution

University of the Bay

Profile Components **LOI**

Your Liaisons

University of the Bay HRPP Liaison

Taylor Jansen

Resources

- Find other users
- Find other sites
- Add HRPP Staff / Members
- Request Help
- Join A Training
- Resources

GETTING STARTED

- Complete IREx Setup**
- Confirm SSRP
- Upload Overall Study Approval
- Publish Approval

-OR-

Study Setup

Is the Reviewing IRB a participating research site in the study? ☐ Yes ☐ No **Required**

Would you like to collect local considerations in IREx? ☐ Yes ☐ No **Required**

Do you require a Letter of Indemnification (LOI) for this study? ☒ Yes ☐ No

Be sure the Study-Specific Reliance Plan (SSRP) also reflects that indemnification is required for this study. This is the last question on the SSRP.

LOI Name **Required**

LOI Template No file chosen **Required**

Available now in IREx!

TRACKING LETTERS OF INDEMNIFICATION (LOIs)



Step 1: Add the LOI your institution requires when serving as the Reviewing IRB

The name you provide will be listed on the Official Notification of Reliance letter when a site indicates reliance.



Site Agreements: University of the Bay

Your Institution's LOI External LOIs

Your LOI

Name

Template

Browse... No file selected.

Save



A copy of the LOI template will be provided to sites that need to sign it.

TRACKING LETTERS OF INDEMNIFICATION (LOIs)



Step 2: List sites that need to sign your LOI

Your Institution's LOI **External LOIs**

The **Carnegie** Letter of Indemnification
(Addendum to the SMART IRB Master Agreement) v. 06/13/2018

LOI Template Edit LOI

Add A Site

Faraday Institute of Research, Scien...

Date Sent

10/08/2018

Date Executed

mm/dd/yyyy

Agreement

Choose File LOI Templa... Copy.docx

Notes

08/10/2018 -- Sent LOI to Study Team

Save Site

LOI Sites

Carnegie University Medical Center	
Central Ohio Medical Center	
Eastman Medical Center of Ohio	✓
Peabody Institute of Medicine	✓
University of the Bay	✓

- Search and enter manually
- OR
- Add sites to your study
 - PSites added to a study that requires an LOI will be added to your list

TRACKING LETTERS OF INDEMNIFICATION (LOIs)



Step 3: Track your institution's LOI: Updating LOI status

The Carnegie Letter of Indemnification
(Addendum to the SMART IRB Master Agreement) v. 06/13/2018

LOI Template Edit LOI

Add A Site

Select a site

Date Sent

mm/dd/yyyy

Date Executed

mm/dd/yyyy

Agreement

Choose File No file chosen

Notes

Save Site

LOI Sites

Name	Status
Oregon Health & Science University	
Peabody Institute of Medicine	✓
Date Sent	8/15/2018
Date Executed	10/10/2018
Document	LOI - LeadSiteSigned_IRBExecuted.pdf
Comments	Aug 15 - Sent LOI to PI
	Aug 31 - Sent reminder to complete LOI to PI
	Sept 12 - LOI routed to Peabody Legal Office for Review
	Sept 25 - Call with Peabody Legal to review LOI. Changes requested cannot be accommodated
	Sept 30 - Peabody Legal has agreed to sign LOI after internal discussion
	Oct 5 - Received signed LOI from study coordinator
	Remove Edit
Penn State Milton S. Hershey Medical Center	✓

For each site, you can enter:

- Site name
- “Date Sent” LOI to site
- “Date Executed” LOI with site
- Upload executed LOI document
- Add notes about correspondence

TRACKING LETTERS OF INDEMNIFICATION (LOIs)



Step 3: Track your institution's LOI: Updating LOI status

Reviewing IRB Approvals | Relying Site Approvals | **Status Summary**

Participant Status Summary Manage LOI Export Data

Search: med

Site	SMART IRB	LOI	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Baystate component - Western Mass Med Ctr	✓	✓	✓	Contacted 02/07/2019		
Carnegie University Medical Center	✗	✓	✓	Started 02/05/2019	0 / 3 Surveys Complete	Not Approved
Eastman Medical Center of Ohio	✗	✗	✓	Started 02/13/2019	0 / 3 Surveys Complete	Not Approved
Hartford College of Medicine	✓	✓	✓	Started 02/01/2019	3 / 3 Surveys Complete	Not Approved
Mellon University Medical Center	✗	✓	✓	Notify HRPP		
Midwest University Medical Center	✓	✓	✓	Started 02/11/2019	0 / 3 Surveys Complete	Not Approved
MUMC component - Peabody Institute of Medicine	✓	✓	✓	Add PI Info		
Peabody Institute of Medicine	✓	✓	✓	Completed 02/01/2019	1 / 3 Surveys Complete	Not Approved

The Carnegie Letter of Indemnification (Addendum to the SMART IRB Master Agreement) v. 06/13/2018

[LOI Template](#) [Edit LOI](#)

Eastman Medical Center of Ohio

Date Sent

1/4/2019

Date Executed

mm/dd/yyyy

Agreement

[Choose File](#) No file chosen

Notes

Cancel

[Save Site](#)

LOI Sites

Name

Status

Name	Status
Albert Einstein College of Medicine	
Baystate Health, Inc	✓
Boston Children's Hospital	
Boston Medical Center	
Carnegie University Medical Center	✓
Case Western Reserve University	
Central Ohio Medical Center	
Children's National Medical Center	
Columbia University	
Columbus University	
Dartmouth College	
Duke University Health Systems, Inc.	
Eastman Medical Center of Ohio	
Emory University	
Faraday Institute of Research, Science and Technology	✓
Georgetown University with Howard University	
Hartford College of Medicine	✓
Harvard University	✓
Icahn School of Medicine at Mount Sinai	

TRACKING LETTERS OF INDEMNIFICATION (LOIs)



Step 4: Track the LOIs you have executed with other institutions

[Your Institution's LOI](#) **External LOIs**

External LOIs

These are other institutions' LOIs which you have executed.

Site	Date Executed	Agreement
Central Ohio Medical Center	01/01/2019	Not Uploaded
Vanderbilt University Medical Center	12/14/2018	LOI_VUMC_Executed_20191214.pdf
University of the Bay		Not Uploaded

Showing 1 to 3 of 3 entries

[Previous](#) **1** [Next](#)

TRACKING LETTERS OF INDEMNIFICATION (LOIs)



Turning LOI tracking on for a study (Reviewing IRBs)

Study Setup

Is the Reviewing IRB a participating research site in the study?

☒ Yes

☐ No

▲ Required

Would you like to collect local considerations in IREx?

☒ Yes

☐ No

▲ Required

Do you require a Letter of Indemnification (LOI) for this study?

☒ Yes

☐ No

Participant Status Summary							
<div> <div>Reviewing IRB Approvals</div> <div>Relying Site Approvals</div> <div>Status Summary</div> </div> <div>Export Survey Data</div>							
<div> <div>Search:</div> </div>							
Site	SMART IRB	IREx Access	LOI	Reliance Decision	Local Considerations	Approval Status (current version)	
Univ of the Bay component - University of the Bay School of Medicine	✓	✓	✓	Completed 11/12/2018	2 / 3 Surveys Complete	Not Approved	
University of the Bay	✓	✓	✓	Completed 10/26/2018	2 / 3 Surveys Complete	Not Approved	
Univ of the Bay component - University of the Bay University Hospital Systems	✓	✓	✓	Started 10/26/2018	0 / 3 Surveys Complete	Approval Not Ready	
Vanderbilt University Medical Center	✓	✓	✓	Started 10/29/2018	0 / 3 Surveys Complete	Approval Not Ready	
Carnegie University Medical Center	✗	✓	✓	Contacted 10/26/2018		Approval Not Ready	
Central Ohio Medical Center	✓	✓	✗	Add PI Info		Approval Not Ready	

TRACKING LETTERS OF INDEMNIFICATION (LOIs)



Completing Agreements for a study (Relying HRPPs)

GETTING STARTED

- ✓ Register
- ✓ Add Study Team
- ➡ Complete Agreements**
- ➡ Confirm Institutional Profile
- ➡ Indicate Reliance
- ➡ Complete HRP Survey
- ➡ Remind PI To Complete PI Survey
- ➡ Awaiting Reviewing IRB Approval

Required Agreements

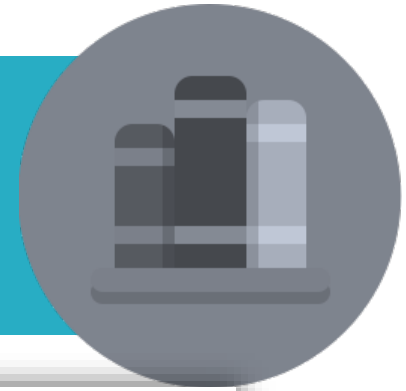
SMART	Your site has signed the SMART IRB agreement.	✓
LOI	<p>Your site must sign the LOI from Vanderbilt University Medical Center before you can indicate reliance.</p> <p>LOI Template from the Reviewing IRB LOI Template.docx</p> <p>Reviewing IRB Liaison Please send any questions and return the executed LOI to Taylor Jansen</p>	✗

Note:

- Must complete agreements to indicate reliance
- Can begin documenting local considerations while working on agreements

Export Status Summary Tab

EXPORT THE STATUS SUMMARY TAB



Reviewing IRBs and IREx Study Managers can generate a CSV download of the status summary tab

Reviewing IRB Approvals | Relying Site Approvals | **Status Summary**

Participant Status Summary

Search:

Export Data ▼

- Export Local Considerations
- Export Status Summary Tab**

Site	SMART IRB	LOI	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Carnegie University Medical Center	✓	✓	✓	Completed 12/04/2018	3 / 3 Surveys Complete	Approved
Central Ohio Medical Center	✓	✗	✓	Contacted 12/04/2018	0 / 3 Surveys Complete	Approval Not Ready
Columbus University	✗	✓	✓	Add PI Info	0 / 3 Surveys Complete	Approval Not Ready
Eastman Medical Center of Ohio	✗	✓	✓	Add PI Info	0 / 3 Surveys Complete	Approval Not Ready
Midwest University Medical Center	✓	✓	✓	Completed 12/07/2018	3 / 3 Surveys Complete	Not Approved
Peabody Institute of Medicine	✓	✓	✓	Started 12/07/2018	0 / 3 Surveys Complete	Not Approved
University of the Bay	✓	✗	✓	Notify HRPP	0 / 3 Surveys Complete	Approval Not Ready

EXPORT STATUS SUMMARY TAB

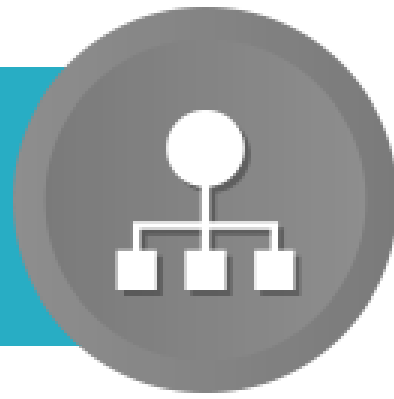


- The Status Summary Tab download includes:
 - Site name
 - FWA holder name
 - FWA number
 - Agreement status
 - SMART IRB, LOI, IREx Access
 - Reliance Decision Status
 - Dates Contacted, Started, and Completed
 - Local Considerations Completion (if applicable)
 - Date IP Confirmed
 - Date HRP Survey Completed
 - Date PI Survey Completed and Validated by HRPP
 - Approval Status for the current version



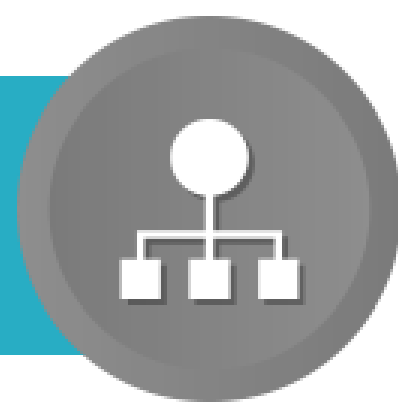
Managing FWA Sites Engaged

MANAGING FWA SITES ENGAGED FOR A STUDY



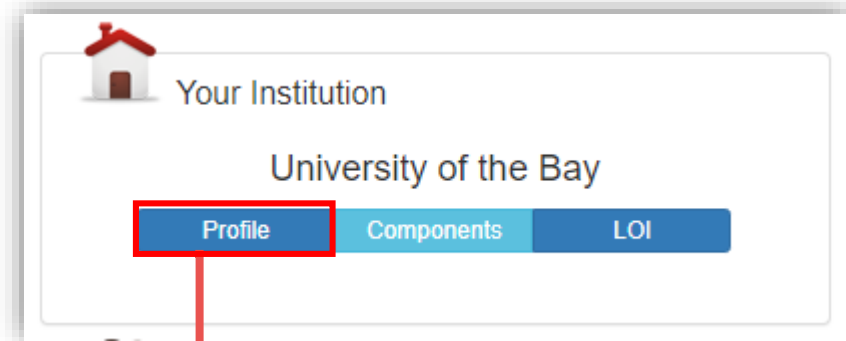
- Correctly identifying **which sites are engaged for a study** can be difficult
 - Eg:
 - Component sites under the same FWA
 - Separate FWA institutions that share an IRB
 - Study teams that engage multiple FWAs institutions
 - PIs with dual appointments
- Currently no easy way to do this in IREx
 - **Coming soon:** *Relying Institutions will have the ability to indicate which FWA sites are engaged for a study*

MANAGING FWA SITES ENGAGED FOR A STUDY



What can I do now?


- 1) Ensure the correct **FWA number** is listed in your Institutional Profile



Institutional Profile

View Profile: University of the Bay

Click the 'edit profile' button on the right to edit your institutional profile.




[edit profile](#)

ABOUT THE INSTITUTIONAL PROFILE

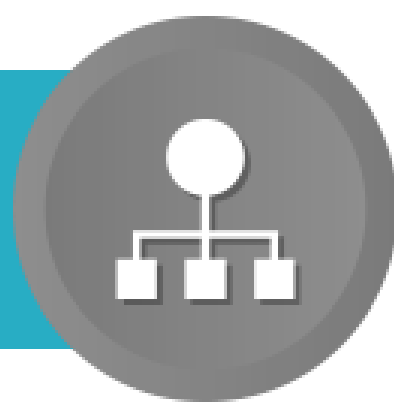
The IREx IP contains basic information about your institution that another institution might use to determine if they feel comfortable relying on, or serving as the Reviewing IRB for, your institution. The IP can also be used by IRBs and study teams to better understand one's institutional processes and requirements when using reliance. This information will be visible to other users in IREx and publicly available as a downloadable PDF on the IREx Website [here](#). This information is for general review purposes only. It may not be accurate and may be subject to change, withdrawn or revised at any time without notice. The Institutional Profile is not intended to serve as a complete record of an Institution's study-specific local considerations.

Section 1: GENERAL HRPP INFORMATION

Institution	University of the Bay
Federalwide Assurance (FWA) #	FWA0001221
FWA Expiration Date	2022-07-04



MANAGING FWA SITES ENGAGED FOR A STUDY



What can I do now?

2) Ensure the correct **component sites** are listed in IREx

Components

List your FWA's component sites that may rely on an IRB in IREx. Component sites do not get access to IREx; you will be able to make cede decisions and provide local context on their behalf.

As the FWA-holder of a component site, you are responsible for providing the relevant local considerations for component sites in your Institutional Profile and for specific studies, as requested by the Reviewing IRB.

University of the Bay School of Engineering	Sch of Engineering	
University of the Bay School of Nursing and Family Health	Sch Nursing & Fam Health	
<p><i>This site is listed as a participant in the following projects</i></p> <ul style="list-style-type: none"> Blood pressure outcomes in neonatal intensive care unit (NICU) graduates with idiopathic hypertension: Demonstration Study A Cluster Randomized Multi-center Baseline Assessment of Carbon Dioxide Emission (ACE) Measuring Levels of Baseline Radiation Exposure in Urgent Care Visits (RADIATE II) 		
University of the Bay University Hospital Systems	Univ Hospital Systems	

Add a component:

Name	Short Name	
------	------------	--

Cancel Save

Click **x** to remove site from the list

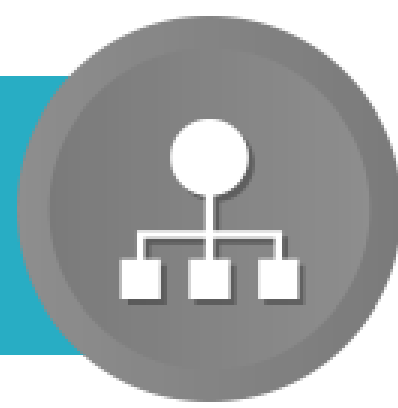
Click to view the studies this component site is listed on

Enter name and click **+** to add a component site to the list

Click **Save** to save changes

Note: You may have components listed. We pulled in components from OHRP

MANAGING FWA SITES ENGAGED FOR A STUDY



Why should I list my component sites?

- + Delineate where research is happening
- + Allows for multiple, separate study teams to be engaged on the same study
- + *Coming soon: indicate which sites are engaged in research for a study*

*Note: Component sites **DO NOT** have liaisons or Institutional Profiles. The FWA site's liaisons perform all actions in IREx for their component sites (e.g., ceding review, providing local considerations)*

Reviewing IRB Approvals

Relying Site Approvals

Status Summary

Manage LOI

Export Data

Participant Status Summary

Search:

Site	SMART IRB	LOI	IREx Access	Reliance Decision	Approval Status (current version)
University of the Bay	✓	✓	✓	Completed 04/22/2019	Not Approved
Univ of the Bay component - University of the Bay School of Nursing and Family Health	✓	✓	✓	Completed 04/22/2019	Not Approved

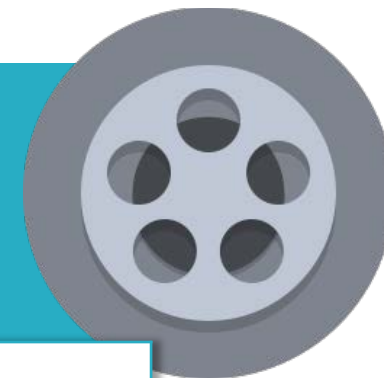
FWA Holder

FWA Component

IREx Resources Update

IREX QUICK GUIDES

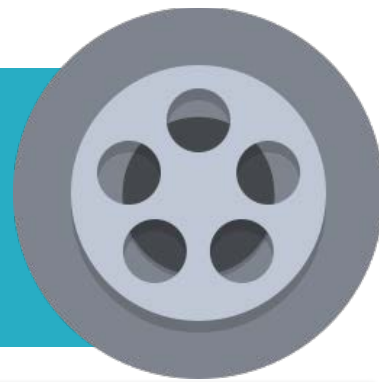
<https://www.irbexchange.org/p/resources/>



Title	Target Audience
Using IREx as the Reviewing IRB	Reviewing HRPPs
Using IREx as the Participating Site HRPP	Participating Site HRPPs
Using IREx as a Multi-Site Liaison	<ul style="list-style-type: none">• Participating Site HRPPs• Reviewing IRBs
Completing the Institutional Profile	<ul style="list-style-type: none">• Participating Site HRPPs• Reviewing IRBs
NEW Adding & Removing FWA Component Sites in IREx	<ul style="list-style-type: none">• Participating site HRPPs• Reviewing IRBs
Adding & Removing Study Team Members from a Study in IREx	<ul style="list-style-type: none">• Coordinating Center Staff or Lead Study Teams• Participating site study teams• Participating site HRPPs
Adding & Removing HRPP/IRB Staff in IREx	<ul style="list-style-type: none">• Participating site HRPPs• Reviewing IRBs
Adding & Removing Participating Site Access to Studies in IREx	<ul style="list-style-type: none">• Reviewing IRBs• Coordinating Center Staff or Lead Study Teams
Capturing Local Considerations in IREx	<ul style="list-style-type: none">• Participating Site HRPPs• Reviewing IRBs
NEW Using IREx to Track Letters of Indemnification (LOIs)	<ul style="list-style-type: none">• Participating Site HRPPs• Reviewing IRBs
Using IREx to Fulfill SMART IRB Documentation and Notification Requirements	<ul style="list-style-type: none">• Participating Site HRPPs• Reviewing IRBs
NEW Adding Study-wide and Site-specific Amendments	<ul style="list-style-type: none">• Reviewing IRBs• Coordinating Center Staff or Lead Study Teams

IREX VIDEOS ON YOUTUBE

<https://www.youtube.com/channel/UCVXKpNczhIPcsQRwF7oWcwA/videos>



Video Title	Target Audience	Length	Link
How to: Register and Cede Review	Participating Site HRPPs	4 mins	https://www.youtube.com/watch?v=-yW-TS-z6So
What is the Study Specific Reliance Plan (SSRP)?	<ul style="list-style-type: none">Participating Site HRPPsReviewing IRBs	1.5 mins	https://www.youtube.com/watch?v=T9FbOV6oN7U
How HRPP/ IRB Liaisons use the IRB Dashboards	<ul style="list-style-type: none">Participating site HRPPsReviewing IRBs	1.5 mins	https://www.youtube.com/watch?v=TKy0Z9_yhf4
How to: Add/Remove Study Team Members from a study in IREx	<ul style="list-style-type: none">Coordinating Center Staff or Lead Study TeamsParticipating site study teams	2 mins	https://www.youtube.com/watch?v=f_hKS8nqbb8
Using IREx as a Participating Site Study Team	Participating site study teams	4 mins	https://www.youtube.com/watch?v=iKiO47Qslws
What is IREx?	All Users	2.5 mins	https://www.youtube.com/watch?v=NV94eUBylMg
How to: Manage Participating Sites in IREx	<ul style="list-style-type: none">Reviewing IRBsCoordinating Center Staff or Lead Study Teams	4 mins	https://www.youtube.com/watch?v=1sxprbGZN5M
IREx Features for HRPPs/ IRBs	<ul style="list-style-type: none">Participating Site HRPPsReviewing IRBs	4 mins	https://www.youtube.com/watch?v=Xv6xLNAxKBA
IREx Features for Lead Study Teams and Coordinating Centers	<ul style="list-style-type: none">Coordinating Center Staff or Lead Study TeamsParticipating site study teams	4.5 mins	https://www.youtube.com/watch?v=KoBAytIY5Cw
How to: Create a Study	Reviewing IRBs	6 mins	https://www.youtube.com/watch?v=xli8YXgDlN4
How to: Add Study-wide and Site-specific Amendments	<ul style="list-style-type: none">Reviewing IRBsCoordinating Center Staff or Lead Study Teams	9 mins	https://www.youtube.com/watch?v=vIrEUIV-BMY&t=2s

Next Call

- July 19, 2019 @ 1 PM ET/10 AM PT